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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
2163	14

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/400,365	CHARBEL ET AL.	
	Examiner	Art Unit	
	Kyle J. Choi	2163	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28 and 52-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28 and 52-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 8, 2002 has been entered.

2. The following is a non-final Office Action in response to the communication filed October 25, 2001. By the amendment:

Claims 29-50 have been cancelled [see below];
Claims 1-28 have been amended; and
Claims 52-55 have been added [see below].

Claims 1-28, 52-55 are now pending in this application and have been examined on the merits as discussed below.

Response to Amendment

3. The amendment filed with the RCE on October 25, 2001 requests that the submitted claim set be substituted for the claims pending in the application. In the request, applicant states "[t]he substitute claim set is intended to reflect the

cancellation of claims 29-50...." However, applicant never explicitly cancelled claims 29-50 in the received amendment. In order to advance prosecution, applicant's statement above was taken as applicant's intent to cancel claims 29-50 and therefore was been entered as such. **Hence, claims 29-50 stands cancelled.**

4. In the above-mentioned amendment, applicant requests that "claims 51 through 55" be added. However, there is no claim 55. Only claims 51-54 have been presented as new.

Moreover, the numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). In the present case, claim 51 was attempted to be added in the amendment filed October 10, 2000. However, a subsequent amendment filed February 1, 2001 as a "Substitute Amendment" cancelled claim 51 filed in the previous amendment and only presented claims 1-50 for entry. Since claim 51 was once presented and cancelled, applicant cannot present another claim

numbered "51" in accordance with Rule 126 as stated above. In order to further prosecution, the claims have been renumbered as follows:

Misnumbered claims 51-54 have been renumbered as 52-55.

Specification

5. The **title** of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. In particular, the feature of conforming the circulation model to a specific arterial anatomy of the living subject should be included somewhere in the title.

6. The **disclosure** is objected to because of the following informalities:

The specification still makes reference to Appendix A (page 25), Appendix B (page 36), and Appendix C (page 36). All of these references, and any others that the examiner may have missed, should be amended to refer to --Microfiche Appendix A-- (B, or C).

Appropriate correction is required.

Information Disclosure Statement

7. The Information Disclosure Statement (IDS) filed on April 20, 2001 has been considered. An initial copy of the Form 1449 is enclosed herewith.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the **first paragraph** of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. **Claims 25-28** are rejected under 35 U.S.C. **112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have now amended claims 23-28 to recite a "system" for modeling circulation. In particular, claims 25-28 recite various "processors". However, there is no support in the specification for these individual "processors" as originally filed. The specification, at best, discloses that

the present invention is directed to a general-purpose computer adapted to perform various functions based on a computer program. There is no support for a separate "correction processor" (claim 25), a correction processor further comprising a "pixel processor" (claim 26), a pixel processor further comprising a "distance processor" (claim 27), or a pixel processor further comprising a "tracing processor" (claim 28). Applicant is invited to indicate where in the specification there is support for these various "processors" in order to overcome this rejection.

10. The following is a quotation of the **second paragraph** of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 21-28, 55 are rejected under 35 U.S.C. **112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to **claims 21 and 22**, these claims recite "means using" an equation. This is not a "means-plus-function" claim under §112, 6th paragraph, since it is not a "means for" performing a

function. Rather, claims 21 and 22 currently recite means that "uses" the recited equation. It is vague and indefinite as to whether applicant is reciting means "for" performing a function or means "using" a recited parameter. Clarification is required. For examination purposes, examiner is construing claims 21 and 22 as reciting "means for calculating the flow based on a Navier-Stokes momentum equation" and "means for calculating the flow based on an equation of state relating a local pressure to a local artery size", respectively.

As to **claim 23**, a blood flow measurement device for obtaining a flow measurement from the living subject "so that the model may be forced with one or more flow parameters corresponding thereto". Moreover, the flow processor is adapted to calculate a flow "based upon the corrected and forced model". However, there is no "forced model" recited in the claims. At best, the flow measurement device collects measurements "to be used" in generating a forced model, but it is not understood how a flow measurement device generates a forced computer model. It seems a modeler or a simulator would be using the measured data and generates a forced model, not the measurement device. Hence, it is vague and indefinite as to where the "forced model" is coming from. For purposes of examination, examiner construes

the "flow processor" to generate a force model based on the measured information from the measurement device and then performs a calculation based on the corrected and forced model.

As to **claim 25**, it is vague and indefinite as to how a correction processor further "comprises" a cursor. A cursor is a non-physical entity made of electrons generated on a computer screen to indicate where the user interaction is occurring on the screen. It is respectfully submitted that a processor cannot be comprised of a cursor. For purposes of examination, examiner construes claim 25 as reciting a correction processor "adapted to generate a cursor for selecting a vessel of the model".

As to **claims 26-28**, in addition to the §112, 1st paragraph rejections above, it is vague and indefinite as to what the applicant is claiming as the components of the system. For instance, claim 26 recites that the correction processor "further comprises" a pixel processor. Does this mean the correction processor chip is functioning in tandem with a coprocessor chip for processing pixels? Or does it mean there is a subprocessor on board the correction processor for processing? As explained above in the §112, 1st paragraph, no such support can be found in the specification as originally

filed. Claims 27 and 28 also suffer the same deficiencies since it is not clear whether applicant is reciting coprocessors or subprocessors incorporated onto the mother chip. Reading the claims as currently recited (claim 28 depends on claim 27 which depends on claim 26), the recited invention seems to comprise a correction processor which has integrated thereon a pixel processor as its subprocessor and the pixel processor has integrated thereon a distance processor and a tracing processor as subprocessors. However, it is vague and indefinite as to the relationship between these processors and more importantly, there is no support in the original disclosure for such a structure.

Response to Arguments

12. In response to applicant's arguments concerning parent application 09/243,870, the following rejections made in the prior Office Action have been withdrawn:

a. All Double Patenting rejections.

b. §102(f) rejection.

c. Rejections based on Kamm et al.

In particular, applicant states that parent application 09/243,870 has been abandoned in favor of the present

continuation-in-part application. Since the application in which the conflicting claims exist has been abandoned, the above-mentioned rejections no longer apply. Hence, those rejections have been withdrawn.

With regard to the rejections based on Kamm et al. (US Pat. No. 6,117,087), examiner has reviewed the provisional application (60/073,580) on which applicant claims priority and is satisfied that the claimed subject matter is sufficiently supported in the provisional application. Hence, the present application has the effective filing date of February 3, 1998, which invalidates Kamm et al. as prior art. Hence, those rejections have been withdrawn.

13. Applicant's arguments with regard to the art rejections, however, have been fully considered but they are not persuasive. Applicant's only argument regarding the outstanding §102/§103 rejections is that none of Charbel #1, Charbel #2, Karplus, nor Foutrakis references teaches the feature of "forcing the model of the circulatory system with one or more flow parameters corresponding to a flow measurement obtained from the living subject" (Response, page 8). Examiner respectfully disagrees based on the following reasons.

a. Charbel #1 (Poster Presentation: "Validation and Clinical Potential of a Computerized Model of the Cerebral Circulation"), a summary of the presentation made by the inventors of the present application, specifically states:

> The model's sophistication is reflected by its ability to simulate flows and pressures in "near physiological" conditions...From a baseline of 108 vessels, the system is ***easily reconfigured*** to include [specific parameters] ***reproducing each patient's individual anatomy***. (Emphasis added; p. 113, col. 1, ¶1).

b. Charbel #2 (Poster-Cerebrovascular: "predictive Value of a Computerized Model of the Cerebral Circulation"), a summary of the presentation made by the inventors of the present application, specifically states:

> The ability to reliably ***simulate such procedures in a given patient*** could increase the likelihood of selecting the optimal one...The computer program is a one-dimensional, explicit, finite-difference algorithm based on a conservation of mass equation, a Navier-Stokes momentum equation, and an equation of state relating local pressure to size of artery. ***Any multivessel network configuration can be specified. The model is forced*** by one or more pressure- or flow-time signatures...A baseline 101-vessel network is used, including the circle of Willis...When surgical anastomoses are supplied, the number of vessels can rise as needed...Aneurysms can also be simulated at various sites. (Emphasis added; p. 166, §27).

c. **Karplus** ("Simulation and Visualization of the Fluid Flow Field in Aneurysms: A Virtual Environments Methodology") specifically states:

> The entire modeling, simulation and visualization methodology...is seen to entail the following distinct steps.
>
> 3.1 Image Acquisition: Prior to undergoing the endovascular procedure (perhaps on the preceding day), the patient's head is scanned using magnetic resonance imaging (MRI)...This facilitates the automatic or semiautomatic detection of the spatial boundaries (the wall) of the aneurysm and of the nearby blood vessels....
>
> 3.2 Boundary Identification: It is now necessary to express the geometry of the walls of the aneurysm...***The boundary geometry is then re-expressed in terms acceptable to the simulation software.***
>
> 3.3 Simulation: This key step entails the numerical solution of the mathematical model describing the physical flow characteristics of the blood flowing through the aneurysm and adjacent blood vessels...the fluid flow is modeled as a system of nonlinear partial differential equations (the Navier Stokes Equations) in the three space dimensions and in time. The field is then discretized by ***replacing the continuous space and time variables by an array of irregularly-spaced points*** to form the finite element grid.
>
> Suitable CFD algorithms are then ***invoked to provide the solution variables for all points in space at successive time levels***. In this way, the pressure and fluid velocity is calculated for all points in time and space interior to the aneurysm.... (Emphasis added; pp. 37-38).

d. Foutrakis ("Construction of 3-D Intracranial Arterial Meshes from Magnetic Resonance Aniography") specifically states:

> Finite element methods are well-suited for solving problems in arterial fluid dynamics, primarily due to their ability to handle flows in complex geometries. In order to develop a realistic model of pulsatile flow in intracranial arteries and associated aneurysms, ***it is necessary to first accurately reconstruct the unique geometry of specific cerebral arteries in the computational domain***...Herein, we introduce an efficient method to accurately develop realistic 3-D computational meshes of human intracranial arteries and aneurysms from serial MRA images...The 3-D volume mesh accurately describes the intracranial arterial geometry and ***will be used to develop patient-specific computational fluid dynamic models of flow phenomena*** in intracranial arteries and aneurysms.... (Emphasis added; Abstract).

Contrary to applicant's assertions, at least the recited passages above all indicate, explicitly and implicitly, that patient specific parameters of the patient's circulatory system are obtained and these specific parameters are used in a computer simulator thereby "forcing" the simulator to simulate the circulatory system based on patient-specific information to produce patient-specific simulation results.

14. Due to applicant's substantial amendments to the pending claims, new grounds of rejections are set forth below, albeit based on the same references. Due to the numerous references that are applied in the following rejections, the Office Action has been formatted based on the "primary reference" applied and therefore may appear to be redundant. For the sake of clarity, all applicable statutory provisions will be cited below and will not be repeated in each of the subsections.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the

> art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

***Rejections based on* Karplus**

17. Claims 1-28, 52-55 are rejected under 35 U.S.C. **102(b)** as being anticipated by **Karplus** *("Simulation and Visualization of the Fluid Flow Field in Aneurysms: A Virtual Environments Methodology")*, previously cited.

As to **claims 1, 12, 23**, Karplus discloses a simulation system and method of obtaining specific vessel parameters of a patient and "forcing" a simulation based on the obtained model

of the specific vessel to simulate flow characteristics of the flow based on the obtained parameters. (p. 38, §3.3) It is respectfully submitted that anytime specific data is used to modify a general model, the resulting simulation based on the specific data is "forced" to simulate the model based on the specific information. Consequently, it is respectfully submitted that Karplus teaches this feature.

As to **claims 2, 13, 24**, Karplus teaches obtaining specific vessel parameters in the brain. This inherently includes the Circle of Willis. (p. 38, col. 1, ¶1)

As to **claims 3, 4, 14**, the simulation includes surgical alterations. (p. 40, col. 2, ¶4)

As to **claims 5-8, 16-19, 26-28**, Karplus teaches obtaining images of the vessels, obtaining boundary information using pixel analysis and meshing, and determining specific parameters of the vessel to be used in the simulation. (p. 37, §3.1; p. 38, §3.2)

As to **claims 9-11, 20-22**, Karplus teaches using Navier-Stokes (p. 38, §3.3), one-dimensional finite difference method (p. 40, col. 1, ¶2), and equations related to pressure and size of arteries (p. 38, col. 2). It is important to note that Ortega (see below) also teach using Navier-Stokes equations for

performing the simulation. Charbel #2 (see below) also teaches that the recited equations are well known (at least since 1994). Additionally, based on applicant's own disclosure, the recited equations are standard in the art of simulating circulatory systems and therefore is considered to be obvious to one of ordinary skill in the art to use these equations.

As to **claims 15, 52, 55**, Karplus teaches using Magnetic Resonance Imaging. (p. 37, §3.1)

As to **claim 25**, a cursor is inherent in all computer systems and therefore is encompassed in Karplus.

As to **claims 53 and 54**, Karplus teaches Doppler flow data to simulate and validate in vivo experimental data.

Rejections based on Foutrakis

18. Claims 1-8, 12-19, 23-28 are rejected under 35 U.S.C. **102(b)** as being anticipated by **Foutrakis** *("Construction of 3-D Intracranial Arterial Meshes from Magnetic Resonance Angiography")*, previously cited.

As to **claims 1, 12, 23**, Foutrakis teaches obtaining specific parameters of a specified vessel of a patient to be used in simulation. As discussed above, all simulations that use specific parameters are "forced" to simulate the specific

model and therefore are considered to be inherent in Foutrakis' teaching. (Abstract)

As to **claims 2, 13, 24**, Foutrakis teaches applying the imaging analysis on the brain. (Figure1) Therefore, Circle of Willis is considered to be inherent in Foutrakis' teaching.

As to **claims 3, 4, 14**, Foutrakis teaches applying the imaging analysis to simulation of surgical alterations. (Abstract)

As to **claims 5-8, 16-19, 26-28**, Foutrakis teaches obtaining an image of a vessel, applying pixel analysis to obtain boundary information, and ultimately the specific characteristics of the vessel from the boundary information. (Abstract; p. 4, Fig. 2; Fig. 7; p. 12, Fig. 9)

As to **claims 15, 52, 55**, Foutrakis teaches using Magnetic Resonance Angiography. (Abstract)

As to **claim 25**, a cursor is inherent to a computer system and Foutrakis teaches the ability to select each vessel. (p. 3, top of Fig. 3)

19. Claims 9-11, 20-22 are rejected under 35 U.S.C. **103(a)** as being unpatentable over **Foutrakis** in view of **Charbel #2**

(Posters-Cerebrovascular: "Predictive Value of a Computerized Model of the Cerebral Circulation"), previously cited.

Foutrakis teaches the recited invention as discussed above. Although Foutrakis teaches using the obtained parameters to develop a model to be used in a finite element computational fluid dynamics model (p. 12), Foutrakis does not specifically teach performing the simulation using the recited equations.

Charbel #2 discloses that it is old and well known to use a one-dimensional, explicit, finite-difference algorithm based on a conservation of mass equation, a Navier-Stokes momentum equation, and an equation of state relating local pressure to size of artery, in simulating patient-specific circulation systems. (p. 166, §27, ¶2)

It would have been obvious for one of ordinary skill in the art at the time of the invention to have used the recited equations in performing the circulatory simulation because Charbel #2 teaches that such equations were already well known in the art and one with ordinary skill would have used the more effective modeling equations available to provide accuracy, especially when the results are to be used in surgical procedures.

20. Claims 53 and 54 are rejected under 35 U.S.C. **103(a)** as being unpatentable over **Foutrakis** in view of either **Karplus** or **Ortega** *("Predicting Cerebral Aneurysms with CFD")*, previously cited.

Foutrakis teaches the recited invention as discussed above. Foutrakis does not teach that the flow measurements are performed using Doppler technology.

Karplus, as discussed above, teaches using Doppler flow measurements to correct and validate simulation results. (p. 40, col. 2, ¶4)

Ortega discloses using Doppler flow measurements to be used in Computational Fluid Dynamics simulation (CFD).

It would have been obvious for one of ordinary skill in the art at the time of the invention to have used Doppler technology to correct and validate simulation results as taught by Karplus/Ortega in the simulation as taught by Foutrakis because Karplus/Ortega teaches that such correction/validation techniques using Doppler is well known to one of ordinary skill in the art to verify predicted results with actual results.

***Rejections based on* Charbel #1**

21. Claims 1-4, 12-14, 23-25 are rejected under 35 USC **102(b)** as being anticipated by **Charbel #1** *(Poster Presentation: "Validation and Clinical Potential of a Computerized Model of the Cerebral Circulation")*, previously cited.

As to **claims 1-4, 12-14, 23, 24**, Charbel #1 discloses a computer simulation using a computerized model that is specifically tailored to "any distensible vessels of various shapes, lengths and configurations" (which inherently would included the Circle of Willis) that is "reconfigured to include stenoses, bypasses and natural or imposed anatomoses" (i.e., surgical perturbations) thereby "reproducing each patient's individual anatomy" (p. 113, col. 1, ¶1). Inputting specific parameters and alterations to reproduce each patient's individual anatomy into a general purpose circulatory flow simulator inherently "forces" the simulation to calculate the flow for a specific patient based on the "corrected" and "forced" simulation (i.e., the general model is "corrected" with specific parameters of a patient and using such a model inherently "forces" the simulation to return a result specific to the patient).

As to **claim 25**, a cursor is inherent in all computer systems and therefore is encompassed in the teaching of Charbel #1.

22. Claims 5-8, 15-19, 26-28, 52, 55 are rejected under 35 U.S.C. **103(a)** as being unpatentable over **Charbel #1** in view of either **Karplus** or **Foutrakis**.

Charbel #1 discloses the recited invention as discussed above. Charbel #1 does not teach how the specific parameters are collected. Specifically, Charbel #1 does not teach obtaining boundary measurements (e.g., diameter of the vessel and tracing ends of the vessel) using image/pixel analysis to determine the measurements of the vessels of the living subject.

Karplus, as discussed above, teach obtaining boundary and cross-section information of specified vessels using MRI technology for the purpose of inputting the gathered information into a circulation simulator for generating a specific simulation result for a specific patient. (p. 38, §3.2)

Foutrakis, as discussed above, teach obtaining boundary and cross-section information of specified vessels using MRI technology for the purpose of inputting the gathered information into a circulation simulator for generating a specific

simulation result for a specific patient. (Abstract; p. 4; Figure 7; p. 12)

It would have been obvious for one of ordinary skill in the art at the time of the invention to have used Magnetic Resonance Imaging technology to obtain the specific parameters of a specific vessel as taught by Karplus and Foutrakis to be used in the simulation as taught by Charbel #1 because Charbel #1 already teaches tailoring a simulation using specific parameters of a vessel of a patient and Karplus/Foutrakis both teach it is well know to obtain such information using MRI technology in the manner recited.

23. Claims 9-11, 20-22 are rejected under 35 U.S.C. **103(a)** as being unpatentable over **Charbel #1** in view of either **Karplus** or **Foutrakis** as applied above, further in view of **Charbel #2**.

The **combination** of Charbel #1 and either Karplus or Foutrakis discloses the recited invention as discussed above. The combination does not specifically teach each of the equations recited in claims 9-11, 20-22.

Charbel #2 discloses that it is old and well known to use a one-dimensional, explicit, finite-difference algorithm based on a conservation of mass equation, a Navier-Stokes momentum

equation, and an equation of state relating local pressure to size of artery, in simulating patient-specific circulation systems. (p. 166, §27, ¶2)

It would have been obvious for one of ordinary skill in the art at the time of the invention to have used the recited equations in performing the circulatory simulation because Charbel #2 teaches that such equations were already well known in the art and one with ordinary skill would have used the more effective modeling equations available to provide accuracy, especially when the results are to be used in surgical procedures.

24. Claims 53 and 54 are rejected under 35 U.S.C. **103(a)** as being unpatentable over **Charbel #1** in view of either **Karplus** or **Ortega**.

Charbel #1 teaches the recited invention as discussed above. Charbel #1 does not teach that the flow measurements are performed using Doppler technology.

Karplus, as discussed above, teaches using Doppler flow measurements to correct and validate simulation results. (p. 40, col. 2, ¶4)

Ortega discloses using Doppler flow measurements to be used in Computational Fluid Dynamics simulation (CFD).

It would have been obvious for one of ordinary skill in the art at the time of the invention to have used Doppler technology to correct and validate simulation results as taught by Karplus/Ortega in the simulation as taught by Charbel #1 because Karplus/Ortega teaches that such correction/validation techniques using Doppler is well known to one of ordinary skill in the art to verify predicted results with actual results.

***Rejections based on* Charbel #2**

25. Claims 1-4, 12-14, 23-25 rejected under 35 U.S.C. **102(b)** as being anticipated by **Charbel #2**.

Charbel #2 discloses a computer program and method for simulating surgical procedures on a patient that alters circulation systems. The computer program is for any multivesseled network configuration, including the Circle of Willis, as well as surgical anatomoses supplied to the vessels. The computer program applies one-dimensional, explicit, finite-difference algorithm based on a conservation of mass equation, a Navier-Stokes momentum equation, and an equation of state relating local pressure to size of artery to obtain computerized

model of the cerebral circulation and its concurrent simulation results. (p. 166, §27)

26. Claims 5-11, 15-22, 26-28, 52-55 are rejected under 35 U.S.C. **103(a)** as being unpatentable over **Charbel #2** in view of **Karplus**.

As to **claims 5-8, 15-19, 26-28, 52, 55, Charbel #2** discloses the recited invention as discussed above. Charbel #2 does not teach how the specific parameters are collected. Specifically, Charbel #2 does not teach obtaining boundary measurements (e.g., diameter of the vessel and tracing ends of the vessel) using image/pixel analysis to determine the measurements of the vessels of the living subject.

Karplus, as discussed above, teach obtaining boundary and cross-section information of specified vessels using MRI technology for the purpose of inputting the gathered information into a circulation simulator for generating a specific simulation result for a specific patient. (p. 38, §3.2)

It would have been obvious for one of ordinary skill in the art at the time of the invention to have used Magnetic Resonance Imaging technology to obtain the specific parameters of a specific vessel as taught by Karplus to be used in the

simulation as taught by Charbel #2 because Charbel #2 already teaches tailoring a simulation using specific parameters of a vessel of a patient and Karplus teaches it is well know to obtain such information using MRI technology in the manner recited.

As to **claims 9-11, 20-22**, Charbel #2 already teaches using these equations as discussed above.

As to **claims 53 and 54,** Charbel #2 does not teach that the flow measurements are performed using Doppler technology. However, Karplus, as discussed above, teaches using Doppler flow measurements to correct and validate simulation results. (p. 40, col. 2, ¶4)

It would have been obvious for one of ordinary skill in the art at the time of the invention to have used Doppler technology to correct and validate simulation results as taught by Karplus in the simulation as taught by Charbel #2 because Karplus teaches that such correction/validation techniques using Doppler is well known to one of ordinary skill in the art to verify predicted results with actual results.

Requirement for Information Under 37 C.F.R. §1.105

27. Applicant and the assignee of this application is required under 37 C.F.R. §1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

The information is required to enter in the record the art suggested by the applicant as relevant to this examination in the disclosure provided in Charbel #1 and Charbel #2 as applied above. In particular, Charbel #1 and Charbel #2 are both summaries of a presentation apparently made by the inventors of the present application. Charbel #1 was a presentation made in San Antonio, Texas at the First Annual Meeting of the Joint Section on Cerebrovascular Surgery of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons on January 1996. Charbel #2 was a presentation made at the 44th Annual Meeting of Congress of Neurological Surgeons in Chicago, Illinois on October 1994. **The examiner requests any materials used, displayed, published, and/or otherwise disclosed at these presentations directed to the computer program for simulating circulatory systems as disclosed in the abstracts used in the rejections above.**

The fee and certification requirements of 37 C.F.R. §1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 C.F.R. §1.105 that is included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 C.F.R. §1.105 are subject to the fee and certification requirements of 37 C.F.R. §1.97.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 C.F.R. §1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained will be acceptable as a complete response to the requirement for that item.

In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pates, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is

not indicated, the subject matter found in applicant's disclosure.

This requirement is an attachment of the enclosed Office Action. A complete response to the enclosed Office Action must include a complete response to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office Action.

Conclusion

28. No claims allowed.

29. This Office action has an attached requirement for information under 37 C.F.R. §1.105. A complete response to this Office Action must include a complete response to the attached requirement for information. The time period for reply to the attached requirement coincides with the time period for reply to this Office Action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kyle J. Choi** whose telephone number is **(703)306-5845**. The examiner can normally be reached on Monday-Friday, 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Tariq Hafiz** can be reached on **(703)305-9643**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the **Receptionist** whose telephone number is **(703)305-3900**.

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington D.C. 20231

or faxed to:

(703)746-7238 [After Final communications, labeled "Box AF"]

(703)746-7239 [Official communications]

(703)746-5548 [Informal/Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand delivered responses should be brought to Crystal Park 2, 2121 Crystal Drive, Arlington, VA, 4th floor receptionist.

KYLE J. CHOI
PRIMARY EXAMINER

Art Unit 2163
March 25, 2002